[1] The committee should evaluate the proposed revisions to Section 1215.1.(b) with respect to the changes in the law. This subsection defines forensic alcohol analysis. Prior to the passage of SB1623, the statutes contained separate descriptions of the analysis of blood, urine, or tissue samples by or for law enforcement agencies (i.e., former H&S Code Section 100710), and the testing of breath samples by or for law enforcement agencies (i.e., former H&S Code Section 100715). SB 1623 repealed both of these sections and the new law [H&S Code Section 100700(a)] now refers generally to "Laboratories engaged (emphasis added) in the performance of forensic alcohol analysis tests by or for law enforcement agencies on blood, urine, tissue, or breath…" The new law, in effect, redefines forensic alcohol analysis, and now combines the tests performed in a forensic alcohol laboratory by "trained laboratory personnel" and the testing of breath samples, which is normally conducted outside the laboratory by trained law enforcement personnel. Accordingly, the revisions proposed by the subcommittee to limit forensic alcohol testing to laboratory personnel, i.e., "forensic alcohol analysts" and to exclude the analysis of breath samples does not appear to be consistent with the new law.

Section 1215.1.(b) could be revised as follows:

1215.1.(b) "Forensic Alcohol Analysis" means the ~~practical application~~use ~~of specialized devices,~~ instruments~~, and methods~~ by trained ~~laboratory~~ personnel ~~forensic alcohol analysts~~ to measure the concentration of ~~ethyl~~ alcohol in samples of blood, breath, urine, or tissue of persons involved in traffic accidents or traffic violations.

Note: the issue of the appropriateness of distinguishing forensic and breath alcohol analysis occurs several times in the draft regulations [e.g., 1215.1.(i), 1216.1.(a), 1216.2.(a),1222.1.(a), and 1222.1.(a)(7)]

[2] Under Section 1215.1.(c), the word "examination" is awkward here. The committee may prefer to replace "an examination" with "a test."

[3] Consistent with the discussion under Section 1215.1.(b), under Section 1215.1.(e), the committee should consider whether the distinction between forensic and breath alcohol analysis is appropriate here, since the statute [H&S Code Section 100700(a)] now refers to "forensic alcohol analysis tests of…breath…" It may be preferable to simply define a forensic alcohol laboratory as a place that performs any of the activities authorized under these regulations and to then separately list the laboratory activities associated with the forensic alcohol analysis of blood, urine and tissue samples, and also breath samples.

Section 1215.1.(e) could be revised as follows:

1215.1.(e) "Forensic Alcohol Laboratory" means a place that performs activities authorized under these regulations. These may be activities of a laboratory engaged in activities other than alcohol analysis.
(1) The activities authorized under these regulations include:

(A) Laboratory analysis to measure the concentration of ethyl alcohol in samples of blood, urine, or tissue of persons involved in traffic accidents or traffic violations.
(B) Determining the accuracy of breath alcohol instruments, and;
(C) Supervising the training of operators of breath alcohol instruments.

[4] Consistent with the discussion under Section 1215.1.(b), under Section 1215.1.(f), the committee should consider whether the definition of a forensic alcohol analyst should include the activities in support of breath alcohol analysis authorized under the regulations.

Section 1215.1.(f) could be revised as follows:

1215.1.(f) "Forensic Alcohol Analyst" means a person ~~employed by~~who is an employee of a forensic alcohol laboratory who performs the ~~technical procedures~~ methods of forensic alcohol analysis, supervises the training of breath instrument operators, or determines the accuracy of breath testing instruments, and meets the qualifications specified in section 1216.2.

[5] To be consistent with the use of the term method under Article 6, under Section 1215.1.(g), the definition of a method here should be revised to specify that the samples analyzed are blood, urine, or tissue. Section 1215.1.(g) should be revised as follows:

1215.1.(g) "Method" means the steps used by a ~~trained person~~forensic alcohol analyst to make a measurement of alcohol concentration in a sample of blood, urine, or tissue.

[6] Under current Section 1215.1.(m), regarding the proposed deletion of the definition of "alveolar;" see comments below for Section 1219.3. (Endnote 36).

[7] See comments provided for Section 1220.1.(a)(2) (Endnote 47) regarding the need to include a definition of internal standard. If the committee determines that a definition of internal standard is needed, a more complete definition would be:

"'Internal Standard' is a known quantity of a compound added to a solution containing an unknown quantity of analyte. The concentration of analyte is then measured relative to that of the internal standard."

[8] None of the proposed definitions of "employee" here appears to capture the employment relationship between the forensic alcohol laboratories and law enforcement agencies.

[9] The proposed definition of "standard" here is not needed given the proposed definitions of primary and secondary standards.

[10] The proposed definition of "blank standard" is not needed. The reference to a blank (i.e., sample without alcohol) is well understood by the regulated community.

[11] The proposed definition of a primary standard as a water-alcohol solution is not correct and also not consistent with the subsequent use of the term under Section 1220.2.(a)(1)(A), which refers to a "primary standard, such as…(NIST) potassium dichromate…" An appropriate definition of primary standard as used in the regulations would be: "'Primary Standard' means a material that is chemically pure, of known chemical equivalence and stoichiometry, stable, and can be dried and weighed out for the preparation of solutions of accurately known concentrations for use in the analysis of alcohol using a direct oxidimetric method." The committee should note that alcohol does not meet these criteria. The definition of primary standard was previously contained in guidelines published by the Department.

[12] The comments included above for the definition of a primary standard (Endnote 11) apply here. (Note: the proposed text here, "Secondary standard…created by the forensic alcohol laboratory from a primary standard" suggests that material from which the secondary standard is prepared would be more correctly described as a stock solution.)

An appropriate definition of secondary standard taken directly from current Sections 1220.2.(a)(1) and 1220.2.(a)(1)(A) of the current regulations would be:

"Secondary alcohol standard" means a water solution of alcohol used to calibrate methods for forensic alcohol analysis.

[13] The committee should consider whether the as undefined term, "Reference alcohol/water or a dry gas alcohol sample" can be clearly defined. It should be noted that the combination here refers to alcohol in two physical states. It would appear to be preferable to describe the procedures for delivering the sample of known alcohol concentration used to determine the accuracy of a breath-testing instrument. This will require a separate definition of a "dry gas calibrating unit" and a "wet-bath calibrating unit." The requirements for the preparation and use of the two devices are different. These requirements were previously described in guidelines published by the Department. As discussed below under Section 1221.4. (Endnote 71), the committee may wish to incorporate procedural requirements that employ the definitions of "wet bath" and "dry gas" calibrating units. Appropriate definitions of calibrating units are shown below:

(z) "Calibrating Unit" means a device that provides a reference sample of known vapor alcohol concentration used to determine the accuracy of a breath testing instrument.
(1) "Dry Gas Calibrating Unit" means a device containing a pressurized mixture of alcohol in an inert gas that provides a reference sample of known vapor alcohol concentration.
(2) "Wet Bath Calibrating Unit" is means a device that provides a reference sample of known vapor alcohol concentration by passing air through a heated water solution of known alcohol concentration.

[14] Regarding the proposed new definition of procedures, the committee should note that there are several general references to "procedures" in regulations. Consequently, it does not appear to be appropriate to limit the use of the term procedures to breath alcohol analysis. Rather, it is better to rely on the common, general dictionary definition of procedure here. (i.e., a series of steps followed in a definite order to accomplish a task).

[15] The committee should consider the following additional definitions, which are intended to clarify and make specific the requirements of the current regulations:

Calibration

A definition of the term, "calibration" is necessary to explain references in the regulations to calibration of a method [i.e., current Section 1220.(b)(2)] and also "calibrated" [i.e., Section 1220.2.(a)(1)]. This definition was previously contained in guidelines published by the Department.

"Calibration" means the process of determining the relationship of the method response in the analysis of a secondary alcohol standard to the concentration of the standard.

Direct oxidimetric method

A definition of the term, "direct oxidimetric method" is needed to explain subsequent references in the regulations [i.e., 1220.2.(a)(1)(A) and 1221.4.(a)(1)(E)]. This definition was previously contained in guidelines published by the Department.

"Direct oxidimetric method" means a method used for the quantitative determination of the alcohol present in an aqueous alcohol sample where the sample is directly mixed with and completely oxidized by a primary standard.

Tissue sample

Anatomically speaking, blood is a tissue. The definition of tissue here including the qualifier, "solid" serves to distinguish tissues other than blood (e.g., organs, muscle) from blood.

"Tissue sample" means a solid specimen of celluler material obtained from the human body

[16] Under Section 1216.1.(a)(1) of the current regulations, the committee should consider the need to retain the requirement that forensic alcohol analysis and also the activities in support of breath alcohol analysis shall be performed only by personnel qualified under the regulations (i.e., either the single class, forensic alcohol analysts, as proposed by the subcommittee or multiple class qualifications as provided by the current regulations).

[17] As discussed under Section 1215.1.(b) (Endnote 1), the distinction in the section title between forensic alcohol analysis and breath alcohol analysis does not appear to be supported by the new law. H&S Code Section 100700(a) refers to, "forensic alcohol analysis tests…on blood, urine, tissue, or breath…" As such, "breath alcohol analysis" is a specific subset of forensic alcohol analysis. The title of Section 1216.1. should be revised to "Qualifications of Forensic Alcohol Analysis Laboratories."

[18] Under Section 1216.1.(a)(1), the committee should consider retaining the requirement that a laboratory employ and utilize the services of persons qualified to perform forensic alcohol analysis (i.e., only forensic alcohol analysts as currently proposed).

The committee should also consider the need to qualify supervisorial staff who can be responsible for all aspects of the performance of forensic alcohol analysis. The current regulations set forth specific experience requirements for supervisors (i.e., "two years of experience in performing forensic alcohol analysis, such experience to include experience in interpretation and correlation of alcohol analyses with subjective observations of the demeanor and behavior of persons who have ingested known amounts of ethyl alcohol; or, in lieu of such two years of experience, satisfactorily completes a training course approved by the Department…"). There are no requirements regarding background or experience of staff in the revised regulations as proposed.

[19] Under Section 1216.1.(a)(2), the Committee may wish to consider the need to clarify and make specific the actual proficiency test requirements in regulation. More particularly, the committee should consider:

1) A requirement that a laboratory achieve a "satisfactory performance" on a proficiency test. However, here it must be noted that according to ASCLD/LAB guidelines, a "successful completion" of a proficiency test means either obtaining the correct response or taking corrective actions in accordance with laboratory policy.
2) Required laboratory response to an unacceptable performance on a proficiency test. The regulations should clarify and make specific the requirements of H&S Code §107002.(d) by clarifying what constitutes, "test results <that> are inconsistent with expected test results." The committee should consider the need to describe the required corrective action taken in the regulations. Under the Department's current program, a California laboratory that fails a proficiency test is required to provide DHS with a written report of the corrective action taken and experimental data demonstrating that the method following this corrective action again meets the required standard of performance.
3) The required frequency of proficiency testing and whether a laboratory should be required to participate in a proficiency test for each method it uses. The basic ASCLD/LAB requirement of only one proficiency test per year does not appear to be sufficient to adequately monitor the competence of the laboratories. Chemical standards and reagents degrade, instruments fail over time, etc. For this reason, laws and regulations covering clinical and workplace drug testing require three

proficiency tests per year. The Department currently conducts three tests per year. Another reason for more frequent proficiency tests is that it gives a laboratory that fails a test, a chance, after correcting the analytical problem, to quickly demonstrate with a subsequent successful proficiency test that it's back on track. Testing once a year would mean that it would take a year for a laboratory to re-demonstrate its proficiency.

4) Applicability of ASCLD/LAB guidelines to non-accredited labs. The ASCLD guidelines for proficiency testing require the accredited labs to meet the requirements of a Proficiency Review Program. This program would not be available to non-accredited laboratories.
5) Finally, the committee should consider whether the requirement under H&S Code Section 100702 that, "All Laboratories…shall follow the American Society of Crime Laboratory Directors/Laboratory Accreditation Board (ASCLD/LAB) guidelines for proficiency testing" means that each laboratory will be required to purchase an ASCLD/LAB technical manual to keep track of updates in order to "follow" the current ASCLD/LAB guidelines.

[20] Consistent with the comments offered under Section 1215.1.(b), (Endnote 1), Section 1216.1.(a)(5) should be revised to clearly state the specific activities of the forensic alcohol laboratory in support of breath alcohol analysis. Section 1216.1.(a)(5) should be revised as follows:

Section 1216.1.(a)(5) ~~Showing ability to meet the requirements set forth in these regulations.~~ ~~Perform~~ Train breath alcohol analysis instrument operators and periodically determine the accuracy of breath alcohol analysis instruments as specified in Article 7.

[21] Under current Section 1216.1.(b), the committee should consider the need to retain the requirement that a laboratory maintain its qualifications "at all times." Since the laboratories will be performing forensic alcohol analysis on a continuing basis, it is appropriate to require that they maintain the proper qualifications at all times.

[22] Under Section 1216.2.(a)(1), on line 2, the committee should note that the requirements for coursework in chemistry are reduced here. The current requirements for the forensic alcohol analyst classification are 2 semesters of general chemistry plus a course in quantitative analysis, so there is a reduction in the required chemistry coursework here. To qualify for the current forensic alcohol supervisor class, a person must possess a baccalaureate or higher degree, or an equivalent, in chemistry, biochemistry, or other appropriate discipline as determined by the Department. In evaluating appropriateness of other disciplines, the Department requires completion of upper division coursework in chemistry.

The committee should consider retaining the quantitative chemistry course requirement for the technical, analyst class [current Section 1216.1.(f)(1)]. The Department imposes similar requirements for its various clinical scientist classifications. Quantitative analysis coursework provides instruction in a number of areas of importance to forensic alcohol analysis including: chemical equilibrium, standard states, redox chemistry, gravimetric,

volumetric and titrametric procedures and use of indicators, method calibration, preparation of standards and reference materials, sampling procedures, and the statistical evaluation of data (precision, accuracy, reliability). Modern quantitative analysis courses typically also provide introductions to instrumental analysis covering spectrophotometry and chromatography.

[23] Under Section 1216.2.(a)(2), the committee should consider the need to require that forensic alcohol analyst staff complete a demonstration of analytical competency external to the laboratory. Currently, the Department requires all staff employed in forensic alcohol analysis to successfully complete a proficiency test and written examination. The Department also reviews staff's training, experience, and educational qualifications in order to assure competency of the employees and to enable the Department to meet the mandate of H&S Code Section 100725. The committee should consider the need to retain state-level oversight of the qualification of laboratory personnel.

[24] Under Section 1216.2.(a)(2), the committee should consider the need to provide a more detailed description of the training required to qualify a person to perform forensic alcohol analysis. This could include, a required period of training, the minimum number of samples analyzed, etc. The regulations [Section 1216.1.(f)(3)] currently require each analyst to complete a training period, which includes a minimum of 25 analyses of alcohol concentration in blood samples, at least half of which contain alcohol. The regulations however should recognize the different training requirements for staff of a laboratory that only supports breath alcohol analysis.

[25] Section 1217.3.(c) of the current regulation is apparently proposed for deletion, but was not included as strikeout text, rather it was simply omitted. The text of the current subsection (c) is: "Persons who formerly qualified as forensic alcohol supervisors or forensic alcohol analysts in another laboratory may be required to demonstrate again their ability to meet the requirement of Section 1216.1.(e)(3) or 1216.1.(f)(4) using the method, apparatus and facilities of the forensic alcohol laboratory which newly lists them in such a Report of Change or Discontinuance."

As discussed above, under the comments for Section 1216.2.(a)(2) (Endnote 23), if the committee decides to retain Department's current program which qualifies personnel employed in forensic alcohol analysis, it will need to consider retaining the requirements of Section 1217.3.(c). In general, when someone transfers from one laboratory to another, there will be changes in methods and procedures, and instruments and equipment. It is appropriate to require such staff to demonstrate again their ability to meet the requirements of the regulations "using the method, apparatus and facilities" of the new laboratory.

[26] Under Article 4, which the subcommittee proposed for deletion, the committee should consider retaining the requirement that the Department approve any training intended to qualify personnel under the regulations. This requirement would apply primarily to the breath operator training programs. Nearly every state maintains oversight of this

training, ether conducting the training itself or approving the training, so California's current requirements here are consistent with those found in other states.

[27] Under Section 1219, the committee should consider the need to retain the general language here stating that the identity and integrity of the samples shall be maintained. The primary basis for maintenance of sample identity and integrity is the labeling and chain of custody requirements contained in the "Uniform Standards for the Collection of Blood Samples for Forensic Alcohol Analysis." As discussed immediately below, these standards should be incorporated into the regulations by reference.

More generally, the committee should consider the need to retain the requirement that samples shall be collected and handled in a manner approved by the Department in order to assure the scientific credibility of the collection procedures.

[28] A new subsection, (a)(1), should be added to incorporate by reference the document, "Uniform Standards for Withdrawal, Handling, and Preservation of Blood Samples for Forensic Alcohol Analysis." These standards were adopted by the Department of Health Services, the Department of Justice, and the California Highway Patrol as required by Section 23158(f) of the Vehicle Code. However, while the Uniform Standards are authorized by statute, they aren't specifically named in the statutes. Vehicle Code Section 23158.(f) states, "The department, in cooperation with the State Department of Health Services or any other appropriate agency, shall adopt uniform standards for the withdrawal, handling, and preservation of blood samples prior to analysis." Accordingly, in order to keep the regulated public informed of the requirements it is appropriate to incorporate the specific document in the regulations by reference.

Added Section 1219.1.(a)(1) should be read as follows:

Section 1219.1.(a)(1) Blood samples shall be collected in accordance with the "Uniform Standards for Withdrawal, Handling, and Preservation of Blood Samples for Forensic Alcohol Analysis" adopted pursuant to Section 23158(f) of the Vehicle Code.

[29] See comments under Section 1220.2.(a)(3) (Endnote 55) concerning the apparently unintentional deletion of the requirement to perform duplicate analyses. As discussed under Section 1220.2.(a)(3), the requirement to perform duplicate analyses should be retained. The requirement here under current Section 1219.1.(b) to collect a sufficient volume of sample to allow duplicate analyses supports the requirement of Section 1220.2.(a)(3) and should be retained here.

Regarding any concern that the reference to the collection of "sufficient sample" may be vague, the committee can determine whether be a laboratory would be able to make a determination as to what sample volume would be "sufficient" here and then provide appropriate direction to the personnel collecting the sample. Alternatively, the Committee could consider more prescriptive standards stating that the volume of sample collected shall be equal to twice the sample volume used in the chemical test

plus 0.5 mL. (Note: it's impossible to remove 100% of the contents of the sample container.)

[30] The proposed amendments under Section 1219.1.(b) [current Section 1219.1.(c)] are problematic for several reasons:

1) The revisions proposed by the subcommittee would permit the use of alcohols other than ethyl alcohol to clean/disinfect the venipuncture site. Isopropyl alcohol is the most common agent used for this purpose. Isopropyl alcohol is often branded as "rubbing alcohol," however some rubbing alcohol preparations contain ethyl alcohol. In general, it does not seem prudent to allow personnel collecting the blood sample, who in many cases may be technically unsophisticated, to make a judgment as to what kind of alcohol to use to prepare the collection site. The requirements of the current regulations, which prohibit the use of any alcohol or other volatile organic solvent, should be retained.
2) As discussed below, under the comments for Section 1220.1.(a)(2) (Endnote 47) some methods are not able to distinguish ethyl alcohol from other homologous alcohols or other volatile organic solvents. The specificity of these methods is still adequate and appropriate for traffic law enforcement provided that potential interfering substances are not introduced during the collection of the sample. These methods have proven to be serviceable without any problems reported. Accordingly, it is appropriate here to continue to prohibit the use of a volatile organic solvent (including the generic class, alcohol) as an agent used to clean the skin.
3) The proposed text of the regulations, which would now read, "alcohol shall not be used to clean the skin" is vague in that it includes a reference to cleaning the skin, but does not require this or even clarify what this means. Accordingly, the requirement to use a "suitable" aqueous disinfectant should be retained. Moreover, the qualities of a suitable aqueous disinfectant should be defined [see proposed Section 1219.1.(c)(1), below], and the examples of suitable aqueous disinfectants should be retained and updated.

To correct the problems, existing Section 1219.1.(c) should be revised as follows:

(c) Alcohol or other volatile organic disinfectants shall not be used to clean the skin where a ~~specimen~~sample is to be collected. Aqueous benzalkonium chloride (zephiran), ~~aqueous merthiolate~~, aqueous povidone-iodine (Betadine), or other suitable aqueous disinfectant shall be used.
(1) A suitable aqueous disinfectant means a chemical agent dissolved in water, which is capable of destroying microbial flora on the skin surface.

The committee may also wish to clarify the reference to "volatile organic" by including a definition under Section 1215.1.:

"Volatile Organic" means a carbon-based chemical compound that has a high enough vapor pressure to significantly vaporize at room temperatures. This includes the generic class of organic compounds known as alcohols.

[31] The comments immediately above under Endnote 30 regarding the inability of certain methods to distinguish ethyl alcohol from other alcohols or volatile organic solvents apply here. Accordingly, the language prohibiting the use of volatile organic solvents to clean the sample containers should be retained.

[32] Under current Section 1219.1.(f), subject matter experts on the committee should evaluate the requirements for collecting and handling post mortem blood samples including: the addition of preservatives with and without refrigeration [cf. current Section 1219.1.(f)(1)]; the need for cautionary instructions regarding the potential for contamination of the sample [cf. current Section 1219.1.(f)(2)]; and the collection of either arterial and venous blood [cf. current Section 1219.1.(f)(2)].

[33] In response to the Office of Regulations' comments, as discussed above under Section 1219 (Endnote 27), the Uniform Standards for Withdrawal, Handling, and Preservation of Blood Samples for Forensic Alcohol Analysis, which are specifically authorized by VC § 23158(f), specify the exact sample labeling requirements and also the information to be recorded on the sample envelope or other container. The required information here includes: full name of subject, date and time blood drawn, initials/name of person drawing blood, initials/signature of witnessing officer, submitting agency, and geographical location where blood sample was drawn.

Current Section 1219.1. extends the labeling requirements to the sample provided to a defendant. The requirements of the Vehicle Code with respect to the information to be provided to the defendant must be considered here. VC § 23158.(c) states: "Upon the request of the person tested, full information concerning the test taken at the direction of the peace officer shall be made available to the person or the person's attorney."

[34] Under Section 1219.2.(a), the committee should consider retaining the stronger qualifying language, "The only approved urine sample…" By eliminating this qualifier, the proposed new language would read, " A urine sample…" This appears to be vague and to lack the force of a regulation. It implies that there may be alternative collection procedures that would yield an approved sample?

Also under Section 1219.2.(a), the committee should note that the newly added language limiting the collection of urine samples to, "the person involved in a traffic accident or traffic violation," does not appear to be necessary given the context of these regulations and is not included for the collection of blood samples (Section 1219.1.) or breath samples (Section 1219.3.).

[35] Under Section 1219.2., the committee should consider a requirement here for the collection of sufficient sample to permit duplicate determinations analogous to the requirement for the collection of blood samples included under existing Section

1219.1.(b). This requirement is just as applicable for the collection of urine samples as for blood samples. An added Section 1219.2.(b) requiring the collection of sufficient sample to permit duplicate determinations would read as follows:

1219.2.(b) Sufficient urine shall be collected to permit duplicate determinations.

Current Sections 1219.2.(b) and 1219.2.(c) would be renumbered 1219.2.(c) and 1219.2.(d) respectively.

[36] Under Section 1219.3., the committee should retain the specification that the breath sample shall be expired breath that is essentially alveolar in composition, which is proposed here for deletion. The collection of an alveolar (deep lung) sample is fundamental to the theory of operation of breath testing instruments. The procedures employed by breath test operators include steps that ensure the collection of an alveolar sample. Accordingly, this important element must be included here and therefore in the training of operators. The Department's regulations are scientific in nature and this important concept, which establishes the scientific basis for breath testing, should be retained in the regulations.

[37] Under Section 1219.3.(a), the committee should retain the requirement that the observation period prior to the collection of the breath sample be completed as a "continuous" time period, which was proposed by the subcommittee to be deleted. The regulations should also be revised to clarify that the continuous observation period should immediately precede the collection of the sample, and the committee may also wish to consider the qualifications of personnel observing the subject.

In general, the requirements here assure the scientific validity of the breath sample by allowing the detection of certain activities that could yield inaccurate (elevated) results. The scientific requirements for the collection of the breath samples are set by the Department's regulations. The Courts have on a number of occasions looked at the 15-minute observation period. [Some recent cases include: Taxara v. Gutierrez (2003), Hernandez v. Gutierrez (2003), Manriquez v. Gourley (2003)]. In every case, the court looked to the Department's regulations for direction. In Manriquez v. Gourley, the court noted that, "Our foremost aim is to ascertain the intent of the agency issuing the regulation to effectuate the purpose of the law." There does not appear to be any record of the Court asking for less direction from the Department. The Department's regulations are intended to enhance the scientific reliability of alcohol testing.

The subcommittee's comments here explaining the decision to delete the requirement for continuous observation, namely that the regulations should "allow the courts to decide the adequacy of the observation" and the subsequent comment, "that it is unreasonable to require the forensic alcohol laboratories to have to deal with this as a requirement" are unpersuasive. As discussed above, the courts evaluate the adequacy of the collected samples based on the Department's regulations. Forensic alcohol laboratories "deal with" the requirements of breath collection primarily though the training of law enforcement personnel to operate the breath testing instruments. One

can only assume that eliminating the requirement that the observation of the subject be continuous would mean that this element would be eliminated from the breath operator training. The consequence of this would be that the scientific basis for breath testing in California would be diminished

[38] The committee should consider amending Section 1219.3.(a) to add the use of mouth spray, gum, or mints to the list of prohibited activities during the 15-minute observation period prior to the collection of a breath sample. Each of these activities could potentially interfere with breath alcohol analysis and the activities can easily be monitored.

[39] Under the newly added section, 1219.3.(b), the committee should consider deleting the descriptions of the requirements for the analysis of a breath under Section 1219.3., which describes the collection of samples. These analytical requirements are best left under Article 6, Requirements for Breath Alcohol Analysis, as shown in the current regulations.

[40] In response to the Office of Regulations' question as to whether the Department's regulations under Article 6 are needed. The answer would be, "Yes." The regulations are needed to satisfy the mandate under H&S Code Section 100703.(d) that the regulations must "ensure the competence of the laboratories and employees to prepare, analyze, and report the results of the tests and comply with applicable laws."

[41] Under Section 1220.(a), on line 1, the committee should consider replacing "have written descriptions" to "prepare written descriptions." The more active verb, "prepare," more clearly connotes the need to maintain detailed and up-to-date written descriptions of the laboratory's method(s) for forensic alcohol analysis.

[42] Under Section 1220.(a), on line 2, the committee should consider retaining the qualifiers, "detailed and up-to-date" in order to provide direction to the laboratories in their preparation of the written method descriptions.

[43] Under Section 1220.(a)(2), the committee should note that a complete written description of a forensic alcohol method would include: the procedures for collection and handling samples, lists of reagents and equipment used, the procedures for standardization of secondary alcohol standards, the calibration procedures, a definition of a sample set, the quality control program for the method, the procedures for calculating and reporting of results, and the maintenance of required records. These elements are all standard components of a laboratory's written method description and in each case can be referenced to other requirements under the regulations. Section 1219 sets forth the requirements for the collection and handling of samples. Section 1220.2.(a)(1)(B) describes the requirements for determining the concentrations of the secondary standards. Section 1220.4. describes the requirements for reporting results, and Section 1222.1. describes the requirements for the maintenance of records of forensic alcohol analysis. The number of samples included in a "set" is an important characteristic of the method with respect to the application of the requirements of the

Section 1220.3.(a)(4), i.e., “At least one sample of the quality control reference material shall be analyzed with each set of samples…”

Section 1220.(a)(2) should be amended to revise the specification of the minimum required elements of the written description of a method for forensic alcohol analysis as shown below:

1220.(a)(2) Each ~~such~~ description shall ~~include~~specify lists of reagents and equipment used, the procedures for collection and handling of samples, the procedures for standardization of secondary alcohol standards, the steps to the method, ~~the instruments used in the method, the persons qualified to conduct the method~~, definition of a sample set, the calibration procedures for the method as specified in section 1220.2, and the quality control program as specified in section 1220.3, and the maintenance of required records for the method.

[44] Regarding the various standard of performance requirements listed under Section 1220.1.(a), the regulations apparently would allow a laboratory to independently evaluate the ability of its methods to meet the required standards of performance. The Department currently requires the laboratories to submit specific experimental data to demonstrate that a method meets the required performance standards. These data are submitted along with the written descriptions of the method filed with the Department. The committee should consider the need for continued state-level oversight in order to assure proper accountability.

[45] Under Section 1220.1.(a)(1) and the requirement that a method, “shall be capable of the analysis of a reference sample within accuracy and precision limits of plus or minus 5 percent of the pre-determined alcohol concentration…”, the committee should consider revising the regulations here to require that the laboratory “demonstrate” a method’s capability of meeting this performance standard. This is required for the performance standards specified under Sections 1220.1.(a)(3) and 1220.1.(a)(5).

The committee should also consider describing in regulation how this demonstration is accomplished. Currently, DHS defines this requirement and sets forth procedures for experimentally demonstrating that the method meets the required standard of performance. Finally, the committee should consider what circumstances require this demonstration. Currently, anytime a laboratory relocates or changes a method, DHS requires a redemonstration of the method’s ability to meet the required standards of performance.

[46] Under Section 1220.1.(a)(1), on line 3, the committee should note that reference to a sample of “pre-determined alcohol concentration” is vague since it does not describe how the concentration is determined. The regulations also do not specify the reference sample matrix. The Department requires laboratories to demonstrate that their methods meet the required standard of performance using samples prepared in biological matrices and has established procedures for determining the known alcohol

concentrations of the reference samples. The committee should consider whether these requirements should be spelled out in the regulations.

[47] Under Section 1220.1.(a)(2), the subcommittee has proposed to adopt new specificity requirements here by requiring that the method shall be able to distinguish ethyl alcohol from other alcohols and other volatile organic solvents. This new requirement would immediately disqualify the diffusion-oxidation methods employed by laboratories in California. The specificity of the diffusion-oxidation method is still adequate and appropriate for traffic law enforcement provided that potential interfering substances are not introduced during the collection of the sample or the maintenance of the equipment. The diffusion-oxidation methods have proven to be very serviceable with no reported problems. The diffusion oxidation methods are not suitable for postmortem blood or tissue analysis, and this is addressed with the requirements of Section 1220.1.(a)(4) of the current regulations.

[48] Under Section 1220.1.(a)(3), and the requirement that a laboratory "demonstrate" that its method is free from interference from anticoagulants and preservative added to the sample, the committee should consider describing how this demonstration is accomplished. Currently, DHS defines this requirement and sets forth procedures for experimentally demonstrating that the method meets the required standard of performance.

[49] Under Section 1220.1.(a)(5), and the requirement that a laboratory "demonstrate" that its method gives a test result which is always less than 0.01 grams% for alcohol-free subjects, the committee should consider describing how this demonstration is accomplished. Currently, DHS defines this requirement and sets forth procedures for experimentally demonstrating that the method meets the required standard of performance.

[50] Under Section 1220.1.(a)(5), the subcommittee has proposed changing the criterion for evaluating the performance of the method when used to analyze samples from alcohol-free subjects to now require that the result is always less than "0.010%" instead of "0.01%." The committee should note that this does not actually change the performance requirements. The performance requirement is the same whether the 0.01 limit is written with 2 or 3 decimal places. In each case, the acceptable 3-decimal place values would include 0.000, 0.001, 0.002...0.009. Any value equal to or greater than 0.01, including the three decimal place values, 0.010, 0.011, 0.012,... would not be acceptable. Accordingly, there's no "necessity" to make this amendment. Moreover, since this performance requirement here involves subject results, it is appropriate to express the results in conformance with the requirements of Section 1220.4.(b), i.e., expressing the results to two decimal places, deleting the digit in the third decimal place if present.

[51] Under Section 1220.2.(a)(1)(A), on line 3, the committee should consider adding a definition of the term "oxidimetric method" or perhaps "direct oxidimetric method" to emphasize the fact that alcohol is added directly to the oxidizing media in the method

for the quantitative determination of the alcohol present in the aqueous alcohol solutions. A suitable definition (taken from DHS guidelines) would be:

"'Direct oxidimetric method' means a method used for the quantitative determination of the alcohol present in an aqueous alcohol sample where the sample is directly mixed with and completely oxidized by a primary standard."

In addition, the committee should consider regulations that would set forth the required procedures for employing the direct oxidimetric method, e.g., required number of replicate analyses, required precision, number of significant figures used to record results, etc.

[52] Under Section 1220.2.(a)(1)(A), on line 5, the term, "NIST traceable secondary alcohol standards" should be clarified. The committee should note that according to NIST (National Institute of Standards and Technology), this organization currently does not have any criteria or protocols to define "NIST trace ability" for aqueous alcohol standards. NIST does manufacture a suite of aqueous alcohol standard reference materials or SRM's (SRM's 1828B, 1847, and 2891 – 2899). The regulations could be revised to qualify this material as a secondary standard. However, the NIST alcohol SRM's are fairly expensive (~$55 per 1.2 mL ampoule), and there would be an obvious incentive for a laboratory to prepare its own standard and then qualify it by analyzing the new standard concurrently with the NIST SRM by the laboratory's forensic alcohol method. There are two problems with this approach: 1) it would conflict with the requirements of the regulations (proposed Section 1220.2.(a)(1)(A) states, "Each forensic alcohol laboratory shall establish the concentration of each lot of secondary alcohol standards it prepares by an oxidimetric method…"); and 2) the new standard qualified against the NIST SRM by the forensic alcohol method, would be properly characterized as a tertiary standard, not a secondary standard.

The committee should carefully consider the option of retaining the requirement that each laboratory establish the concentration of each lot of secondary alcohol standards it uses, whether prepared or acquired, by an oxidimetric method, which employs a primary standard. Primary standards are commonly used in analytical chemistry. They establish a reference point that helps ensure that the analyses are accurate and reliable. Primary standards are chosen based on very specific characteristics. They must be extremely pure, very stable, and have a high molecular weight. Based on these criteria, alcohol would not qualify as a primary standard. The primary standard and secondary standard should be linked by an absolute chemical method. Qualifying a standard based on an indirect method (e.g., gas chromatography) could introduce errors. Introducing multiple levels of indirect analysis would increase the likelihood of error. The approach required by the current regulations, which involves the direct analysis of the secondary standard based on a primary standard, appears to be superior. Introducing any potential errors in an analytical system, which is designed to yield results that become evidence in legal proceedings, does not seem warranted. .

[53] The committee should carefully evaluate the value of the requirements contained in the newly added Section 1220.2.(a)(1)(B), i.e., "The forensic alcohol laboratory shall verify the concentration of all secondary standards used in the method by analyzing the new secondary standard concurrently with a previously analyzed secondary standard." The new language fails to specify how the analysis would be conducted, but for the sake of discussion it can be assumed that the laboratory's forensic alcohol method would be used here. The current regulations, Section 1220.2.(a)(1)(B), require the laboratory to establish the concentration of the secondary alcohol standard by an oxidimetric method, which employs a primary standard. In terms of the analytical chemistry involved here, the direct oxidimetric method is absolute method. The concentration of the secondary standard is determined directly based on the primary standard and known reaction stoichiometry. The primary standard is very pure, very stable, and can be weighed. Primary standards are commonly employed in analytical chemistry to ensure the highest levels of accuracy.

All forensic alcohol methods are relative methods. They require calibration based on a comparison of method response for an unknown sample with a known standard. Accordingly, the proposal here to verify the concentration of new secondary standard using the forensic alcohol method would involve a comparison with the old standard. However, aqueous alcohol solutions are labile, subject to evaporative losses. Laboratories typically use a given secondary alcohol standard for a year or more. During that time it is possible, even likely, that there will be small losses of alcohol concentrations. Accordingly, using the old standard to verify the new standard can introduce errors. The current regulations address this issue by requiring that each new lot of secondary standard must be referenced back to the primary standard. The committee will need to consider retaining this requirement.

[54] Under Section 1220.2.(a)(2), the subcommittee's proposed revision replacing "secondary standard samples" with "secondary standards" (twice) does not appear to improve clarity. The use of the word "sample" here is completely consistent with the definition of sample under Section 1215.1.(i), i.e., "a representative portion of breath, blood, urine, or tissue or of an artificially constituted material such as a reference or a standard…". The word "sample" in Section 1220.2.(a)(2) correctly refers to an aliquot taken from the larger volume of secondary standard, not the entire volume of secondary standard. Also, the new reference to "standards" (plural) as proposed might suggest that more than one standard sample must be included in the calibration event. In fact, many laboratories currently employ a single analysis of a secondary standard with each run. The committee should consider retaining the current language. See also comments below under Endnote 58.

[55] The draft regulations here inadvertently deleted the current requirement of Section 1220.2.(a)(3) that the unknown samples must be analyzed in duplicate, since the text, "and shall include at least duplicate analyses of samples for forensic alcohol analysis" in the current regulations was omitted. The requirement here has always been interpreted as applying to case samples (i.e., samples taken from persons involved in traffic accidents or traffic violations). Program does not recall any confusion over this. The

inclusion of duplicate analyses as a minimum standard here is completely reasonable. Duplicate analyses significantly increase the confidence in the results by minimizing the impact of random error.

The requirement for duplicate analysis of case samples should be retained, but should be transferred to a separate subsection as shown below:

> **1220.2.(a)(4)** The procedure shall include at least duplicate analyses of samples for forensic alcohol analysis.

Current Sections 1220.2.(a)(4) and 1220.2.(a)(5) would be renumbered 1220.2.(a)(5) and 1220.2.(a)(6) respectively.

[56] The comments under Section 1219.1.(b) (Endnote 30) regarding the inability of certain methods to distinguish ethyl alcohol from other alcohols or volatile organic solvents apply here under Section 1220.2.(a)(4). Moreover, it should be noted that even for the more specific chromatographic methods, washing or rinsing glassware with the alcohol chosen as the internal standard (typically n-propanol or butanol) could cause undetectable interferences (negative).

[57] The subcommittee's comments here are confusing. Section 1220.2. sets standards of procedure. Performance requirements, including accuracy and precision, are set forth under Section 1220.1. Even assuming the laboratory follows the proper procedural steps (analysis of blanks and standards, etc.), the instruments and equipment still need to be in good working order. This status should be routinely checked. The committee should consider retaining language to require this.

[58] Under Section 1220.3.(a)(1), the committee should note that the deletion of the word "material" and the substitution of the word "sample" here does not improve clarity. As noted above, under Section 1220.2.(a)(2) (Endnote 54), the word "sample" is defined in the regulations as a representative portion of another material. The regulations under Section 1220.3.(a)(1) pertain to the larger volume of material (quality control) prepared or obtained by the laboratory, not to an individual sample of that material. Moreover, the new language, which now includes the phrase, "quality control reference sample, a sample of which…" is very awkward. The term, "quality control reference material" is used correctly later in this section.

[59] Under Section 1220.3.(a)(2), on line 2, the committee should consider the need to specify the number of significant figures used to represent the mean alcohol concentration value of the quality control material. Based on the proposed revisions to the specification of the range of alcohol concentrations for the reference material [cf. Section 1220.3.(a)(1)], it would appear that the laboratories should employ three significant figures here.

[60] Under Section 1220.3.(a)(3), it's worth noting that the rule making record shows that the advisory committee in drafting the original regulations selected the current constant

limits, +/- 0.01 grams %, because they were easy to apply. Substituting the +/- 5% range here will result in limits, which are variable and more complicated to apply. For example, for a reference sample with a mean value of 0.123 grams %, the magnitude of the 5% limits would be 0.00615. The committee should consider the need to add a specification of how the +/- 5% limits are applied, including the number of significant figures employed.

[61] Under Section 1220.3.(a)(5), on line 2, the committee should note that the change from "the method shall be regarded in error" to "the forensic alcohol analysis shall be regarded in error" seems unnecessary. The standards of performance (Section 1220.1.) and procedure (Section 1220.2) apply to the forensic alcohol method. When a method, which has been previously demonstrated by the laboratory to meet the required standard of performance, fails to analyze the quality control sample accurately, then the method should be considered to be in error. Moreover, the reference to method here clearly excludes procedures for the forensic alcohol analysis of breath samples.

On lines 4 – 6, the insertion of the phrase, "as shown by return of the analysis of the quality control reference sample to values within the limits specified in (a)(3)" is unnecessary since it is repeated immediately below. Moreover, the language of the current regulations clearly indicates that the corrective action takes place in two steps. First qualified staff identify and correct the source of the error, and then staff demonstrate that the error was corrected by analyzing additional quality control samples. Only after completing this demonstration can case samples again be analyzed. The committee should consider retaining the language of the current regulations here.

[62] The comment "offered" by the subcommittee that the abbreviations for the phrase grams per 100 milliliters of liquid were specified in the Vehicle Code is not correct. The Vehicle Code consistently uses the words "grams of alcohol per 100 milliliters of blood" or alternatively, "percent by weight of alcohol in his or her blood." No abbreviations are used. Despite this, it would appear that limiting the number of abbreviations that can be used to express the quantity grams per 100 mL of liquid seems justified in order to prevent confusion in the court's interpretation of the results of the tests. Alternatively, the regulations could require that a laboratory's report of forensic alcohol method results must include a definition of any abbreviation of the unit, grams of alcohol per 100 milliliters of blood.

[63] Regarding the provisions of Section 1220.4.(c), which permit the reporting of blood alcohol concentrations less than 0.01% as "negative," the Office of Regulations asked, "Why specify in regulation? Does it matter?". The subcommittee apparently concluded that, "this discretion is needed because of other forensic alcohol work, not related to traffic accidents or violations." The full committee should consider the following more complete explanation:

Section 1220.4.(b) requires that any three-decimal place results must first be truncated to two decimal places before reporting. Accordingly, any three-decimal place result less

than 0.01 grams% (e.g., 0.001, 0.002, 0.003...0.009) would need to be reported as 0.00 grams%, which would suggest the complete absence of any alcohol. It's not uncommon for scientists to report levels of analyte concentration that are below a reliable detection limit (or in this case a statutory limit) as "negative." Section 1220.4.(c) provides this option. Since the only alternatives here are reporting "0.00%" or "negative," Section 1220.4.(c) would appear to qualify as a regulation.

[64] Under Section 1221., the committee should consider including the requirement that laboratories prepare detailed, up-to-date written descriptions of the procedures employed in support of breath alcohol analysis performed by law enforcement agencies. These descriptions would include procedures for periodically determining the accuracy of the instruments, and procedures for training instrument operators. The regulations should set forth requirements for contents and availability of the written descriptions. The requirements here would be analogous to the requirements under Article 6, Section 1220. that a laboratory prepare written descriptions of its forensic alcohol method(s).

Written methods and procedures provide a basis for the continuous management and directorship of the individuals working in the forensic alcohol laboratory. The written descriptions have a special significance in the forensic setting. They describe the details of how the laboratory has carried out an analyses or training program. The written descriptions should be available to all participants in judicial process. Again, the laboratories are required to prepare written descriptions of their forensic alcohol methods. The equivalent requirement should be applied here.

Suggested regulatory language is offered below:

(a) Each forensic alcohol laboratory shall prepare detailed, up-to-date written descriptions of the procedures used for the periodic determination of accuracy of breath testing instruments and the procedures used for the training of operators of breath testing instruments.
(1) Such descriptions shall be immediately available to the person performing the procedures and shall be available for inspection by the Department on request.
(2) The descriptions of the procedures for the periodic determination of accuracy of breath testing instruments shall include a specification of the instrument and calibrating unit used, a list of reagents and equipment used, procedures for determining the concentrations of the reference samples, the procedures for performimg the periodic determination of accuracy, procedures for interpreting the results of the periodic analyses of the reference samples, corrective action taken in response to a periodic determination of accuracy result which is outside acceptable limits, and the maintenance of required records.
(3) The descriptions of the procedures for the training of operators of breath testing instruments shall demonstrate compliance with the requirements of sections 1221.4.(a)(3), (A) through (E).

[65] The committee may wish to consider the need to clarify and make specific the requirements of the Health and Safety Code with respect to the use of preliminary

alcohol screening devices or PAS devices to measure alcohol concentration. Section 100700(a) of the Health and Safety Code requires that laboratories engaged in the testing of breath samples by or for law enforcement agencies for purposes of determining the concentration of ethyl alcohol in the blood of persons involved in traffic accidents or traffic violations shall comply with regulations adopted by the Department. Vehicle Code Section 13388, (a) and (b) [Ch 118, Stats. 1998, effective January 1, 1999, Operative July 1, 1999] requires the use of PAS devices to determine alcohol concentrations under certain circumstances. Other Vehicle Code Sections permit the use of PAS devices for the same purpose [e.g., Vehicle Code Section 23612(h) (Ch 938, Stats. 1994, renumbered from 23157(h), Sec 4., CH. 740, Stats. 1998)]. The committee may wish to add language that would clarify and make specific the requirements of the law here by declaring that PAS testing when used to determine the concentration of alcohol (as opposed to merely the presence or absence of alcohol) is subject to all of the requirements of the regulations pertaining to breath alcohol analysis.

Suggested regulatory language here would be:

(1) Preliminary alcohol screening devices when used to measure the concentration of alcohol, as opposed to merely the presence or absence of alcohol, fall under the requirements of these regulations.

[66] Section 1221.1.(b) of the current regulations, which is proposed here for deletion, requires breath alcohol analysis to be under the direct jurisdiction of a governmental agency or licensed forensic alcohol laboratory. The committee should consider whether it is appropriate to try and retain some jurisdictional requirements here.

[67] The current regulations pertaining to breath alcohol analysis include Section 1221.2., Standards of Performance, and Section 1221.4., Standards of Procedure. The structure here mirrors that found under the Article 6 regulations covering blood, urine, and tissue analysis. The revisions proposed by the subcommittee delete Section 1221.2. and rename Section 1221.4., thus eliminating the parallels with the Article 6 regulations. The committee may wish to retain the parallel structure of the current regulations.

[68] Under Section 1221.3.(a), on line 4, the committee should note that the proposed language here referring to, “calibrating instruments”, is not consistent with either the terminology used in H&S Code Section 100701, which refers to “calibrating devices” or the DOT model specifications and conforming products lists which refer to “calibrating units.” More importantly, the use of the word “instruments” here is inconsistent with the definition of this term under Section 1215.1. (i.e., “‘instrument’ means any item or combination of items of equipment used to make a measurement of alcohol concentration.”). The calibrating units are used to provide a sample of known alcohol concentration to check the accuracy of the breath instrument. The calibrating units lack any capability of measuring alcohol concentration.

Proposed regulatory language which addresses the above deficiencies is provided below:

Under Section 1215.1., Definitions

"Calibrating Unit" means a device that provides a reference sample of known vapor alcohol concentration used to determine the accuracy of a breath testing instrument.

Under Section 1221.3.

1221.3. Approved Instruments and Calibrating Units

1221.3.(a) Breath alcohol instruments and calibrating units used in breath alcohol analysis shall meet the requirements specified in Health and Safety Code Section 100701.

[69] Regarding the subcommittee's report that "accuracy determinations are sometimes delegated to the law enforcement agencies after the forensic alcohol laboratory trains someone…," it should be noted again that the regulations (Section 1221.4.(a)(2)(A)1.) require the forensic alcohol laboratory to make the determination as to whether an instrument continues to meet the required accuracy. This responsibility cannot be "delegated" under the current regulations.

[70] The committee should carefully evaluate subcommittee's apparent comments here that it wanted to leave requirements of the regulations regarding the responsibility for determining the accuracy of the instrument "open to interpretation." Writing regulations that are then subject to various interpretations may not satisfy the committee's primary mandate of providing regulations that ensure the competence of the laboratories and employees to prepare, analyze, and report the results of the tests.

[71] Under Section 1221.4.(a)(1)(A), the committee should note that the description here of the analysis of a "reference alcohol/water standard or a dry gas alcohol standard…" is incorrect, since the breath instrument is only capable of analyzing a gas-phase sample. (Note: the units, "grams/210 liters" shown on line 3 would not make sense for an aqueous alcohol sample.)

In general, it would appear to be appropriate to define in regulation the different and separate procedures for delivering a gas-phase sample from a calibrating unit that contains an aqueous-alcohol solution and from a dry-gas sample.

[72] Under Section 1221.4.(a)(1)(A), the committee should consider retaining the requirement that the forensic alcohol laboratory must provide the reference sample employed in the periodic determinations of accuracy. Under the current regulations, the laboratory provides the reference sample. The laboratory is also responsible for determining the known alcohol concentration of the sample, and for assuring the sample is used in a manner which assures that the known alcohol concentration is maintained. These are all key steps, which enable the laboratory to be "responsible" for determining

the accuracy of breath alcohol instruments as required under proposed Section 1221.4.(a)(1).

[73] Under Section 1221.4.(a)(2)(A)1. of the current regulations, the committee should consider retaining the requirements here which set forth the qualifications of the operator of the instrument when performing a periodic determination of accuracy.

[74] Under Section 1221.4.(a)(1)(B), the committee should consider whether the revised language describing the required frequency of the determinations of accuracy of breath instruments is as clear as it could be. For example, could the requirement, "The accuracy determination…shall occur once in either a period of time not exceeding 10 days or following the testing of every 150 subjects, whichever comes sooner" be interpreted as precluding two determinations in that time period? The committee should consider clearer language here.

[75] Under Section 1221.4.(a)(1)(C), the committee should consider describing in regulation who evaluates the results of the periodic analyses of the reference sample to determine whether an instrument continues to meet the accuracy requirements. Section 1221.4.(a)(2)(A)1. of the current regulations requires that the results shall be used by a forensic alcohol laboratory to make this determination. The subcommittee has proposed to delete this section and consequently it is no longer clear who will make this determination. It would appear that the responsibility to make the scientific determination as to the accuracy of the instrument should be reserved for the laboratory.

[76] The committee should consider the value of the new requirements proposed by the subcommittee under added Sections 1221.4.(a)(1), (C) and (D). The language here, which is taken directly from the requirements for the quality control (QC) program under Article 6 for the analysis of blood, urine, and tissue samples (i.e., Section 1220.3.), does not appear to apply to breath alcohol analysis. As required under Section 1220.3., the QC sample is included with each set of case samples. In breath alcohol analysis, where the accuracy determination is performed every 10 days or 150 subjects, as many as 150 subject results could be involved, spanning back to the last satisfactory determination of accuracy. The standard of practice in California has been to require that an instrument, which fails a periodic determination of accuracy, be removed from service. This practice could be incorporated into the regulations as follows:

Section 1221.4.(a)(1)(C) Whenever the analysis of the reference sample is outside the limits specified in (a)(1)(A), the instrument shall be removed from service.

[77] Under Section 1221.4.(a)(1)(E), on line 4, the committee should consider the need to clarify the revisions here which permit a laboratory to purchase "NIST traceable reference standards." NIST (National Institute of Science and Technology) currently does not have any criteria or protocols to define "NIST trace ability" for dry-gas calibrating units. NIST does certify "NIST Traceable Reference Gas mixtures" (NTRM), including ethanol-nitrogen mixtures prepared by manufacturers. Two manufacturers,

Airgas and Scott Specialty Gases have NTRM agreements with NIST, but neither vendor makes the NTRM's available for sale.

The Department currently requires the laboratories to independently determine the alcohol concentration of the samples delivered by a dry gas device. The requirement here is based on Section 1221.4.(a)(2)(A) of the regulations, which requires that the accuracy of the instruments must be determined by the analysis of a reference sample of known alcohol concentration. The committee should consider retaining this requirement.

[78] Under Section 1221.4.(a)(1)(E), on lines 5 – 7, the committee should evaluate the value of the new requirement that the laboratory "verify" the value of the reference alcohol/water or a dry gas alcohol sample concurrently with a previously analyzed reference alcohol/water or dry gas alcohol sample. The procedures involved here appear to suffer the same problems as described in the comments for Section 1220.2.(a)(1)(B) (see Endnote 53). In addition, the procedure described here whereby a breath instrument is used to verify the reference sample concentration and then the reference sample is used to verify the breath instrument's accuracy employs a circularity that could potentially allow instrument errors to go undetected.

[79] Section 1221.4.(a)(4) in the draft regulations should be designated as Section 1221.4.(a)(3). Under this section, the committee should consider the need to clarify what constitutes "supervision" of the operator training. The Department currently interprets supervision as active oversight. This is based on the use of the term supervision throughout the current regulations, which include 21 references to supervision or supervisor. In the proposed new regulations all of the other references to "supervision" have been deleted, and only Section 1221.4.(a)(3) remains. The regulations should clarify and make specific the actual supervision requirements here.

[80] Under Section 1221.4.(a)(2) and the regulations proposed by CACLD, the committee should consider the need to retain the subject, "Precautionary Checklist," as part of the breath instrument operator training. The operator training procedures define the procedure for performing breath testing. The precautionary checklist, required under current Section 1221.4.(a)(3)(D), serves to help document that a given test was properly administered. In many jurisdictions, the precautionary checklist plays a key role in assuring the identity and integrity of the results. These checklists are signed by the officer-operator and are used to record the officer's observations.

[81] The comment by the subcommittee here that it, "did not wish to make specific requirements that curtailed the independence of the labs and agencies in determining the means that best met their training needs for breath alcohol operators" should be evaluated in terms of the basic mandate of the Department's regulations, which is to ensure the competence of the laboratories and employees to prepare, analyze, and report the results of the tests. The current regulations describe the basic training requirements (i.e., theory of operation; detailed procedure of operation; practical experience, etc.). These requirements are essential to provide adequate operator

training. The courts predicate the general admissibility of breath evidence based on the findings: 1) the instrument was in proper working order; 2) the test used was properly administered; 3) the operator was competent and qualified. Items 2 and 3) depend on the adequacy of the operator training. As required by Section 1218, the Department reviews and approves training procedures submitted by the laboratories to make sure that the training is adequate and in compliance with the requirements of the regulations. The State has a vested interest in making sure that this testing is performed correctly to ensure that drunk drivers are properly convicted and that innocent drivers are not prosecuted unjustly because of faulty laboratory testing. This is why the legislature passed laws requiring the regulation of this testing.

[82] The Office of Regulations' description of the findings of the case, "People v. Rawlings" does not appear to be correct. The court did not predicate the admissibility of evidence based on the fact that "statute and regulation did not specify that 'operators' had to be trained". In fact, the court found that DHS' regulations govern breath testing and that these regulations do require the training of operators. The court also made the general finding that neither the regulation nor its parent statute refer to the admissibility into evidence of any tests which fail to comply with the statutes for any reason. The court noted that when the statute does not require the exclusion of evidence (and there are no constitutional issues involved) such evidence is not inadmissible. Statutory compliance or noncompliance merely goes to the weight of the evidence. There have been similar findings in a number of cases; the case most often quoted is People v. Adams (59 Cal. App. 3d 559; 131 Cal. Rptr. 190; 1976), which extended the finding to the admissibility of evidence, which is not in compliance with the regulations. These cases from the early 70's date back almost to the beginning of California's regulation of blood and breath alcohol analysis. They haven't eliminated the importance of DHS' regulations (the defendant can still attack the weight of the non-compliant evidence) and shouldn't be construed as limiting DHS' authority to write regulations.

[83] The committee may wish to consider retaining current Section 1221.4.(a)(5), which is proposed here for deletion. This section authorizes qualified laboratory personnel (i.e., forensic alcohol supervisors, forensic alcohol analysts, or forensic alcohol analyst trainees under the current regulations) to operate a breath-testing instrument without having completed the operator training course. The exemption of laboratory staff from this training requirement is consistent with the higher level of technical skills possessed by the qualified laboratory staff, and of course is also consistent with the qualification of laboratory personnel to supervise regular operator training.

[84] The committee should consider retaining current Sections 1221.4.(a)(6) and 1221.4.(a)(6)(A), which are both proposed for deletion. These sections set forth requirements for the maintenance of records of a laboratory's periodic determinations of accuracy, including records showing the frequency of such analyses and the name of the person who performs the periodic analyses of the reference sample to determine the accuracy of the instruments. Article 8 describes the general requirement that laboratories must maintain records of periodic determination of accuracy. The required

content of these records is described here under Sections 1221.4.(a)(6) and 1221.4.(a)(6)(A) of the current regulations.

[85] Section 1221.4., "Expression of Breath Alcohol Analysis Results" should be designated as Section 1221.5. The committee should carefully consider the impact of the addition of Section 1221.5.(a), in conjunction with the deletion of current Section 1220.4.(f). The effect of these changes would be to prevent the expression of a result obtained with a breath instrument as a blood alcohol concentration. The committee probably needs to consider whether the option of permitting breath results to be expressed either directly as breath alcohol concentrations or as converted blood alcohol results is more appropriate here.

All of the Vehicle Code presumptive and per se DUI laws are written specifically in terms of blood alcohol concentrations. However, in 1989, the legislature amended Vehicle Code Section 23152.(b) (Ch. 1114, Stats. 1989) to provide that, "percent, by weight of alcohol in the person's blood shall be based upon the grams of alcohol per 100 milliliters of blood or grams of alcohol per 210 liters of breath." This amendment became effective in 1992. Subsequently in 1994, an appeals court decision [People v. Bransford (1994) 8 Cal. 4th 885] concluded that per se driving under the influence laws could be applied to breath alcohol concentrations, thus permitting breath test results to be directly reported as breath alcohol concentrations. The committee must determine whether the statutes and decisional law now mandate that breath test results must only be reported as breath concentrations as would now be required in the proposed regulations.

[86] Under Section 1222.1.(a)(1), the committee should consider retaining the current requirement that the laboratories' records be "up-to-date". This requirement was struck out here without any explanation.

[87] Under Section 1222.1.(a)(2), the committee should consider retaining the qualifying phrase "under these regulations," in the specification of the analytical records which must be maintained. It would appear that this qualifier serves to appropriately limit the scope of the record keeping requirements. As described under Section 1215.1.(e), a forensic alcohol laboratory may be engaged in activities other than forensic alcohol analysis.

[88] Under Section 1222.1.(a)(5), the committee should consider retaining qualifying phrase "as a laboratory may perform for law enforcement agencies." This qualification appears to accurately describe the scope of the record keeping requirements here.

[89] Under Section 1222.1.(a)(6), and the requirement to record the names of the instructors, the committee should note that with the revisions proposed in the draft regulations, there are no longer any requirements regarding the qualification of the "instructors" for the breath instrument operator training. As described under Section 1221.4.(a)(4) [Note: it appears that this section should be numbered 1221.4.(a)(3)], the operator training must be "supervised" by a forensic alcohol analyst. Accordingly, it

would appear to be appropriate to maintain records of the person supervising the training.

[90] Under Section 1222.1.(a)(7), and the requirement to maintain records of instrument maintenance, the committee should note that there are no requirements under the regulations regarding the maintenance of the breath testing instruments.

[91] Under Section 1222.2.(a)(4) and the requirement for agencies to maintain records of operators "trained by the agency, including the names of instructors," the committee should again note that with the revisions proposed in the draft regulations, there are no longer any requirements regarding the qualification of the "instructors" for the breath instrument operator training. More importantly, the committee should note that the current regulations [Section 1221.4.(a)(4)] require that training of instrument operators be conducted by the laboratories under supervision of laboratory staff. While the laboratory might certainly call upon an experienced operator to assist in the practical instruction of the trainees, the primary responsibility for the training rests with the laboratory.

The proposed revisions here to the record keeping requirements now suggest that the law enforcement agencies would be independently training the operators. It should be noted that the former *ad hoc* Advisory Committee on Alcohol Determination, a group which included representatives from the crime laboratories, recommended that specially qualified law enforcement personnel (breath test operator supervisors) could be permitted to train other officers, but only after the operator supervisor had received special advanced training from the forensic alcohol laboratory. Representatives on the advisory committee from the laboratories agreed to develop a standardized operator supervisor training course covering the core competencies required for supervising breath instrument operators.

Errata

[E-1] Under Section 1217.2., the struck-out text, "The applicant shall set forth all pertinent information called for by the forms" was inadvertently duplicated here.

[E-2] Under Section 1220.(a), the reference to "licensed" here was apparently inadvertently retained.

[E-3] Under Section 1220.4.(a), on line 1, the text here, "Blood and urine alcohol" is being added to the regulations and therefore should be presented as underlined text.

[E-4] Under Section 1220.4.(a), on line 4, the draft regulations included a period (".") after "%". This should be replaced with a comma (",").

[E-5] Under Section 1221.3.(a), on line 2, the struck out text omitted the phrase "in the Federal Register" which is contained in the current regulations (i.e. "Only such types and models of instruments and related accessories as are named in the "Conforming

Products List" published in the Federal Register by the National Highway Traffic and Safety Administration…").

E-6 This Section should be numbered 1221.5. in the draft regulations.